JC10 Rec'd PCT/PTO 3 1 MAY 2005

|   |   |   | <u> </u>                                   | JUSC ALOMIO  |  |  |  |  |  |
|---|---|---|--|--|--|--|--|--|--|
| FORM PTO-1390<br>(REV. 01-2003)         |   |   | PATENT & TRADEMARK OFFICE                  | ATTORNEY'S DOCKET NUMBER<br>122196                         |  |  |  |  |  |
|   | D   | NSMITTAL LETTER TO THE<br>ESIGNATED/ELECTED OF<br>DICERNING A FILING UNI  | FICE (DO/EO/US)                            | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/518,768 |  |  |  |  |  |
|   |   | IONAL APPLICATION NO.<br>/02787   | INTERNATIONAL FILING DATE<br>March 5, 2004 | PRIORITY DATE CLAIMED                                      |  |  |  |  |  |
|   | TITLE OF INVENTION PREVENTION OF AND COUNTERMEASURES AGAINST MITOCHONDRIAL DISEASE  |   |  |  |  |  |  |  |  |
| APPLICANT FOR DO/EO/US Fukumi MORISHIGE |   |   |  |  |  |  |  |  |  |
| Applic                                  | Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: |   |  |  |  |  |  |  |  |
| 1.                                      |   | This is a <b>FIRST</b> submission of item   | s concerning a filing under 35 U.S.        | C. 371.  |  |  |  |  |  |
| 2.                                      | $\boxtimes$   | This is a <b>SECOND</b> or <b>SUBSEQUE</b>  | NT submission of items concerning          | g a filing under 35 U.S.C. 371.                            |  |  |  |  |  |
| 3.                                      |   | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. |  |  |  |  |  |  |  |
| 4.                                      |   | The US has been elected (Article 3  | 1).  |  |  |  |  |  |  |
| 5.                                      |   | A copy of the International Applicat  | ion as filed (35 U.S.C. 371(c)(2))         |  |  |  |  |  |  |
| Er                                      |   | a. $\square$ is attached hereto (required   | only if not communicated by the In         | iternational Bureau).                                      |  |  |  |  |  |
| •                                       |   | b. $\ \square$ has been communicated by   | the International Bureau.                  |  |  |  |  |  |  |
|   |   | c. $\square$ is not required, as the applic   | cation was filed in the United States      | s Receiving Office (RO/US).                                |  |  |  |  |  |
| 6.                                      |   | An English language translation of  | the International Application as file      | d (35 U.S.C. 371(c)(2))                                    |  |  |  |  |  |
| )                                       |   | a.  is attached hereto.   |  |  |  |  |  |  |  |
| •                                       |   | b.  | ted under 35 U.S.C. 154(d)(4).             |  |  |  |  |  |  |
|   |   | c.  | n was filed in English.                    |  |  |  |  |  |  |
| 7.                                      |   | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))  |  |  |  |  |  |  |  |
|   |   | a.   are attached hereto (required only if not communicated by the International Bureau).   |  |  |  |  |  |  |  |
|   |   | b. ☐ have been communicated by the International Bureau.  |  |  |  |  |  |  |  |
|   |   | c.  have not been made; however, the time limit for making such amendments has NOT expired.   |  |  |  |  |  |  |  |
|   |   | d. ☐ have not been made and will not be made.   |  |  |  |  |  |  |  |
| 8.                                      |   | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).   |  |  |  |  |  |  |  |
| 9.                                      |   | An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).  |  |  |  |  |  |  |  |
| 10.                                     |   | An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).                    |  |  |  |  |  |  |  |
| Items                                   | s 11 t  | o 20 below concern document(s)  | or information included:                   |  |  |  |  |  |  |
| 11.                                     | $\boxtimes$   | An Information Disclosure Stateme   | ent under 37 CFR 1.97 and 1.98.            |  |  |  |  |  |  |
| 12.                                     |   | An assignment document for recor  | ding. A separate cover sheet in co         | empliance with 37 CFR 3.28 and 3.31 is included.           |  |  |  |  |  |
| 13.                                     |   | A preliminary amendment.  |  |  |  |  |  |  |  |
| 14.                                     |   | An Application Data Sheet under 37 CFR 1.76.  |  |  |  |  |  |  |  |
| 15.                                     |   | A substitute specification.   |  |  |  |  |  |  |  |
| 16.                                     |   | A power of attorney and/or change of address letter.  |  |  |  |  |  |  |  |
| 17.                                     |   | A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.  |  |  |  |  |  |  |  |
| 18.                                     |   | A second copy of the published international application under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |  |
| 19.                                     |   | A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).   |  |  |  |  |  |  |  |
| 20.                                     |   | Other items or information:   |  |  |  |  |  |  |  |
|   |   |   |  |  |  |  |  |  |  |

| U.S. APPLICATION NO. (if known, s<br>10/518,768  | PLICATION NO. (if known, see 37 C.F.R. 1.5)  INTERNATIONAL APPLICATION NO. PCT/JP04/02787  |                                |                                     |           | ATTORNEY'S DOCKET NUMBER 122196 |  |  |  |  |
|--|--|--------------------------------|-------------------------------------|-----------|---------------------------------|--|--|--|--|
| 21.  The following fees  | . 51701 54702101   |                                | CALCULATIONS PTO USE ONL            |           |                                 |  |  |  |  |
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| BASIC NATIONAL FEE (37   | CFR 1.492(a)):   |                                | \$ 300.00                           | \$        |                                 |  |  |  |  |
| SEARCH FEE (37 CFR 1.49  |  |                                |                                     | \$        |                                 |  |  |  |  |
| International search fee (37   |  |                                |                                     |           |                                 |  |  |  |  |
| International search report p the search fee is paid   |  |                                |                                     |           |                                 |  |  |  |  |
| All situations not provided fo   | \$ 500.00  |                                |                                     |           |                                 |  |  |  |  |
| EXAMINATION FEE (37 CF   | R 1.492(c)(1)-(2)):  |                                |                                     | \$        |                                 |  |  |  |  |
| International preliminary exa<br>IPEA and favorable as to no<br>for all claims presented in th   | velty, inventive ste   |                                |                                     |           |                                 |  |  |  |  |
| All situations not provided fo   |  |                                |                                     |           |                                 |  |  |  |  |
| Surcharge of \$130.00 for fur earliest claimed priority date   | nishing the oath or (37 CFR 1.492(e)   | declaration later than 3<br>). | 0 months from the                   | \$        |                                 |  |  |  |  |
| TOTAL PAGES OF<br>APPLICATION OVER<br>100 ( - 100)   | ÷ 50   | = †                            | x 250 =                             | \$        |                                 |  |  |  |  |
| tround up to next integer  |  |                                | L                                   |           |                                 |  |  |  |  |
| CLAIMS   | NUMBER FILED   | NUMBER EXTRA                   | RATE                                | \$        |                                 |  |  |  |  |
| TOTAL CLAIMS   | - 20   | =                              | x 50.00 =                           | \$        |                                 |  |  |  |  |
| INDEPENDENT CLAIMS   | - 3  | =                              | x 200.00 =                          | \$        |                                 |  |  |  |  |
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| Applicant claims small e reduced by ½.   | \$   |                                |                                     |           |                                 |  |  |  |  |
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| Processing fee of \$130.00 for the earliest claimed priority   | or furnishing the Erdate (37 CFR 1.49)   | \$                             |                                     |           |                                 |  |  |  |  |
| · · · · · · · · · · · · · · · · · · ·  |  | TOTAL                          | NATIONAL FEE =                      | \$        |                                 |  |  |  |  |
| Fee for recording the enclos accompanied by an appropr   | ed assignment (37<br>iate cover sheet (3   | \$                             |                                     |           |                                 |  |  |  |  |
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| b. 🔲 Please charge n   | D. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this   |                                |                                     |           |                                 |  |  |  |  |
| c. 🕅 The Commission  | sheet is enclosed.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 15-0461. A duplicate copy of this sheet is enclosed. |                                |                                     |           |                                 |  |  |  |  |
| d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. |  |                                |                                     |           |                                 |  |  |  |  |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CER 1.137(a) or (b)) must be filed and granted to restore the application to pending status.                             |  |                                |                                     |           |                                 |  |  |  |  |
| SEND ALL CORRESPONDENCE TO:  |  |                                |                                     |           |                                 |  |  |  |  |
| OLIFF & BERRIDG  | •  | 101111                         | 7                                   |           |                                 |  |  |  |  |
| Customer Number: 25944 NAME: James A. Oliff REGISTRATION NUMBER: 27,075  |  |                                |                                     |           |                                 |  |  |  |  |
| Date <u>May 31, 2005</u>   | ·  | NAME: Jesse<br>REGISTRATIO     | se O. Collier<br>ION NUMBER: 53,839 |           |                                 |  |  |  |  |
|  |  |                                |                                     |           |                                 |  |  |  |  |
| ·  |  |                                |                                     |           |                                 |  |  |  |  |

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Fukumi MORISHIGE

Application No.: 10/518,768

Filed: December 21, 2004 Docket No.: 122196

For: PREVENTION OF AND COUNTERMEASURES AGAINST MITOCHONDRIAL

**DISEASE** 

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date of this non-CPA application, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- 2. The references 1-4 were cited in the International Search Report. An English language version of the International Search Report is attached for the Examiner's information.
- 3. English language Abstracts of the non-English language references 1-2 are attached hereto.
- 4. A computer-generated English language translation of the following Japanese Patent Publication has been obtained from the website of the Japanese Patent Office ([http://www.jpo.go.jp]), and is attached, but has not been reviewed for accuracy. See References 1-2.

Respectfully submitted,

James A. Oliff

Registration No. 27,075

Jesse O. Collier

Registration No. 53,839

JAO:JOC/mps Date: May 31, 2005

OLIFF & BERRIDGE, PLC P.O. Box 19928 Alexandria, Virginia 22320 Telephone: (703) 836-6400 DEPOSIT ACCOUNT USE
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| Form PTO-1449<br>(REV. 8-83)  | US Dept. of Commerce PATENT & TRADEMARK OFFICE |  | ATTY DOCKET NO.<br>122196  |                     |                    | APPLICATION NO. 10/518,768            |           |         |       |              |
|---|--|--|----------------------------|---------------------|--------------------|---------------------------------------|-----------|---------|-------|--------------|
| INFORMATION DISCLOSURE STATEMENT  |  |  |                            |                     |                    |                                       |           |         |       |              |
| (Use several sheets if necessary)   |  |  | APPLICANT Fukumi MORISHIGE |                     |                    |                                       |           |         |       |              |
|   |  |  |                            | FILING I<br>Decembe | DATE<br>r 21, 2004 |                                       |           | GROUP   |       |              |
|   |  | U.S.   | PATI                       | ENT DOCU            | IMENTS             |                                       |           |         |       |              |
| EXAMINER<br>INITIAL   |  | DOCUMENT NUMBER  | ]                          | DATE                |                    | NAMI                                  | AME       |         | CLASS | SUB<br>CLASS |
|   |  |  |                            |                     |                    |                                       |           |         |       |              |
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|   | 1  | FOREIC   | SN PA                      | ATENT DO            | CUMENTS            |                                       |           |         | 1     |              |
|   |  | DOCUMENT NUMBER  | ]                          | DATE                |                    | COUNTI                                | RY        |         | CLASS | SUB<br>CLASS |
|   | 1  | JP A 2003-104882 w/ abst & transl  | 4/9/2003                   |                     | JAPAN              |                                       |           |         |       |              |
|   | 2  | JP A 2003-335664 w/ abst & transl  | 11/2                       | 25/2003             | JAPAN              |                                       |           | ·       |       |              |
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|   |  | ·  |                            |                     |                    |                                       |           |         |       |              |
|   | <del> </del>                                   | OTHER DOCUMENTS (Inc   |                            |                     |                    |                                       | es, etc.) |         |       |              |
|   | 3  | GOTO, "Mitochondrial Myopathy," Vol. 204, No. 3, pp. 193-197 {2003}  |                            |                     |                    |                                       |           |         |       |              |
|   | 4  | KOGA et al., "Novel Therapeutic Trial of L-arginine on Acute Phase of Stroke in MELAS," vol. 75, no. 8, 4S64-4, pp. 753 {2003} |                            |                     |                    |                                       |           |         |       |              |
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| Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |  |  |                            |                     |                    |                                       |           |         |       |              |

Date: May 31, 2005